

A I D S TREATMENT N E W S

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John S. James
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Uganda has had a remarkable decline in HIV prevalence, and the question of what caused this decline is controversial. An intensive study of the Rakai region of Uganda from 1994 - 2003 found that much of the decreased prevalence resulted from death of people with HIV. But the incidence of new HIV infections was low throughout this study and did not change greatly, suggesting that the real cause of the success was a large reduction in new infections before the study began. The early data presented at the February 2005 Retroviruses conference also showed increasing use of condoms, and some backsliding on reducing the number of sexual partners. But neither change was big enough to greatly affect the incidence of new infections, at least in the aggregate data across the 50 villages studied. In summary, the big reduction in HIV prevalence occurred because of changes that happened before this study, not those measured within it. Therefore the new information does not contradict reduction in the number of sexual

AIDS Treatment News

Subscription and Editorial Office:

AIDS Treatment News
Philadelphia FIGHT
1233 Locust St., 5th floor
Philadelphia, PA 19107
800-TREAT-1-2 toll-free U.S. and
Canada
fax: 215-985-4952

email: aidsnews@aidsnews.org

web: <http://www.aidsnews.org>

Editor and Publisher: John S. James

Statement of Purpose:

AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

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partners as a major cause of Uganda's success.

Virginity Pledge Did Not Prevent Sexually Transmitted Infections.....

A major U.S. study of sexually transmitted diseases in young people found that virginity pledges were associated with behaviors that would seem to be protective, and yet had no benefit in preventing disease.

Prison Health Care: *New York Times* Series Brings Attention.....

A three-part series and an editorial in *The New York Times*, the result of a year's investigation, has brought attention to the bad medical care in prisons in the U.S. -- deficiencies that kill prisoners and allow epidemics to spread. The wrong funding arrangements, incentives to make money by reducing care, and the huge growth in the number of prisoners in the U.S. are major causes. We also comment on shortage of social space as a potential root cause of prison and other problems.

HIV Travel Restrictions: Where to Find Help Navigating Them

By Suzy Subways

If you are planning to travel across international borders, take a look at "Quick Reference -- Travel and Residence Regulations for People with HIV and AIDS" compiled by Peter Wiessner and Karl Lemmen of Deutsche AIDS-Hilfe in Berlin, Germany. Updated every two years, it includes details from 169 countries. The Internet version of their latest research (finished in December 2004) is now being made available in English, German and French by David Haerry of Switzerland at <http://www.aidsnet.ch/linkto/immigration>

Any new updates will be posted there first. But also, a complete 2004 "Quick Reference" booklet will be available to download from the website of Deutsche Aids Hilfe at <http://www.aidshilfe.de> (in English and in German).

Most tourist destinations do not restrict

entry to HIV positive visitors who plan to stay for three months or less. Still, 24 of the 169 countries surveyed do frequently deport anyone with HIV. "Quick Reference" offers information for short-term visitors as well as for those seeking visas and residency. While the authors' main sources of information are each country's embassy in Germany and the German embassy in each country -- and the way travelers are treated may depend greatly on their country of origin -- the compiled information is designed for visitors from every nation. It includes details of particular rules for African visitors, for example, who may be more likely to be required by some countries to present (negative) HIV test results at entry.

Wiessner and Lemmen also consulted non-governmental organizations (NGOs) in the countries concerned, the U.S. state department [see "Human Immunodeficiency Virus (HIV) Testing Requirements for Entry into Foreign Countries,"

http://travel.state.gov/travel/tips/brochures/brochures_1230.html], United Nations and World Health Organization publications, and news reports and press releases. They asked about the official regulations of each country -- and how they are carried out in practice. When their sources provided contradictory information, the authors indicate where the different versions came from. Because the research is not definitive, they recommend that all prospective travelers contact AIDS service organizations or other NGOs located in their hopeful destination, and consult people with HIV who have visited there. They list contact information for such NGOs in most countries. Another source for international contacts is NAM's "AIDS Organizations Worldwide"; see <http://www.nam.org.uk/en/orgs/ux/default.asp>.

Peter Wiessner requests that readers contact him (peter-wiessner@t-online.de) or David Haerry (david@hdnet.org) with any information you may have about

regulations in various countries. The authors are eager to supplement their research with as much data as possible, particularly because the information about some nations is contradictory or entirely unavailable. If the 2004 Quick Reference book is not yet on the Web site <http://www.aidshilfe.de>, you may also email Wiessner to request a .pdf copy.

Visiting the U.S.

Despite the consensus among experts that HIV travel bans are unnecessary and harmful to public health (see http://www.iom.int/en/PDF_Files/HIVAIDS/UNAIDS_IOM_statement_travel_restriction_s.pdf), the U.S. still shuts its borders to visitors with HIV. The United States Citizenship and Immigration Service (USCIS) sometimes grants a waiver for HIV positive visa applicants hoping to stay for 30 days or less, according to "Quick Reference." This is for family visits, medical treatment, business travel, or participation in a scientific, health-related conference. Be sure to apply several months in advance, and don't make irreversible travel plans until you hear back -- and you won't hear back until less than 30 days before you hope to enter the U.S. If you are changing planes in the U.S. but not planning to visit, check with your airline about whether you will need to go through customs.

There is no actual HIV test at the airport or border, says Vishal Trivedi, Immigration Project Coordinator at the Legal Services Department of Gay Men's Health Crisis (GMHC) in New York City. But travelers carrying HIV-related literature or HIV medications may be turned over to an immigration official for further investigation, he says. "If there is a determination made by the immigration officer that the traveler is HIV-positive and is traveling without proper HIV waiver clearance, he or she can legally be barred from entry into the United States."

In other words: proceed with caution. "There is no legal requirement that you

keep your pills in the original, labeled bottle in which they came," says Ronda Goldfein, executive director of the Philadelphia-based AIDS Law Project. Many people who take medications on a schedule like to use pill organizers, or an attached set of color-coded smaller pill cases for each day of the week. Still, prepare for any possible scenario. "In general," Trivedi warns, "the Department of Homeland Security and the State Department have wide discretion with regard to enforcement of immigration policies." And assumptions that visitors from particular countries of origin have links to "terrorist groups" or drug smuggling mean they "seem to be scrutinized more routinely," he says.

To be on the safe side, he says, travelers-to-be should consult with an immigration practitioner who is familiar with HIV travel restrictions to the United States. For individual consultation, contact the GMHC Legal Services Department at 212-367-1040 or the AIDS Law Project at 215-587-9377. Questions can also be sent to hotline@gmhc.org. The UK's NAM offers more information about entering the U.S. with medication; see "Traveling with Medication,"

<http://www.aidsmap.com/en/docs/F302D11F-2568-4AF3-9C5F-205ACE027BC1.asp>

Tipranavir: FDA Advisory Committee Will Meet May 19, Hear Experts, Public Comment

On April 4 the FDA announced a one-day meeting of its Antiviral Drugs Advisory Committee on the important new protease inhibitor tipranavir, which is widely expected to be approved soon. The FDA usually schedules these hearings when it when it wants outside advice either on whether to approve a drug, or on other questions such as safety issues, or what

the company can claim as approved uses. We do not yet (April 5) know what questions the FDA plans to ask the committee; there should not be any big surprises, as we would have heard about them already through the trials. But in any case the advisory committee meetings usually provide the public with the most important and complete information available about the drug being considered.

Tipranavir, made by Boehringer Ingelheim, is important because it has a different resistance profile than currently approved protease inhibitors, so those who are already resistant to the existing drugs can benefit from it. In tests so far, those who started tipranavir were more likely to control resistant virus if they also started FUZEON (enfuvirtide, T-20) at the same time, so that they had two new drugs to which they were not resistant.

The FDA meeting will be Thursday, May 19, 2005 from 8 a.m. to 5 p.m. at the Hilton Washington DC/North in Gaithersburg, Maryland, salons A, B, and C. To get to the hotel from Washington, take the Metro Red Line to Shady Grove (the end of the line), and call the hotel for a shuttle, 301-977-8900.

Public comments are scheduled from 1 to 2 p.m.; those wanting to speak should give notice by May 6. Comments can also be submitted in writing, and should be received by May 6.

Detailed background information and meeting material will be available on the FDA's Web site at least 24 hours before the meeting.

For more information see <http://www.fda.gov/oc/advisory/accalendar/2005/cder12531d051905.html>

Note: For recent general information about tipranavir, see the four abstracts from the 12th Retroviruses Conference, February 2005, that mention 'tipranavir' in their title. These can be found through the abstract search at http://www.retroconference.org/Search_Abs tract_2005/ Type in 'tipranavir' (without the quotation marks), make sure that

'Abstract Title' is selected, and click 'Find!'.

Sculptra Facial Treatment; New Physician Locator

By John S. James

On February 28, responding to patient and activist requests, Dermik, the maker of Sculptra (still called New Fill in some countries), added a U.S. physician locator to its Web site,

<http://www1.sculptra.com/US/Locator.do>.

Sculptra is used as a restorative treatment for lipoatrophy (fat wasting) of the face.

Note that "This service is not intended as a recommendation, referral, or endorsement of any particular health care provider or practice, or as a tool for verifying credentials, qualifications, or abilities" (quoted from Web site). It lists physicians using Sculptra who are located near one's ZIP code. Physicians add themselves to the list by submitting a form they obtain from their Sculptra sales representative. So after checking the list, ask a trusted physician for advice -- to help find a doctor who has considerable experience with Sculptra and is well regarded in the medical community.

For more information about Sculptra and similar treatments, see <http://health.groups.yahoo.com/group/PozHealth/> -- an email discussion list with over 1500 members (you do not need to join to read the messages). For information about lipoatrophy, see the Retroviruses conference search in the comment below.

Comment on Avoiding d4T and AZT, in Case of Lipoatrophy

It is best not to need restorative treatments at all. At the 12th Retroviruses Conference (February 2005) there was considerable discussion of switching patients away from thymidine analogs (d4T or AZT; d4T may be particularly important

to avoid) to other regimens such as those using tenofovir or abacavir, if lipoatrophy starts to become a problem. For more information, search the conference abstracts for the 12 that include the word lipoatrophy (see especially abstracts 40, 44LB, and 45LB, which will be included in the search results). Keep in mind that no HIV treatment is without risk, and that people can respond very differently. So those doing well on any regimen may want to stay with it if possible.

The home page for the Retroviruses conference is <http://www.retroconference.org/>. Click on Search Abstracts to search the presentations at the most recent annual meeting.

FDA AIDS Announcements, First Quarter 2005

The U.S. Food and Drug Administration distributed eight announcements on its AIDS list serve in January, February, and March 2005. Each one will be important for some of our readers. You can obtain all of these and any later announcements at the FDA HIV/AIDS List Serve Archive page, <http://www.fda.gov/oashi/aids/listserve/archive.html>

The eight announcements starting with the most recent are:

- * Important information about Sustiva (efavirenz) and pregnancy, 2005-03-31
- * Notice of important new drug interactions (Norvir or Kaletra), 2005-03-30
- * Approval of Baraclude (entecavir) for treatment of chronic hepatitis B virus infection, 2005-03-30
- * Updated guidelines for the use of antiretroviral agents in pediatric HIV infection, 2005-03-24
- * Pegasus and Copegus indications expanded to include treatment of hepatitis C and HIV coinfection, 2005-03-02
- * Drug interaction warning: Saquinavir/ritonavir and rifampin, 2005-02-08
- * FDA warning - unapproved home-use

diagnostic test kits, 2005-02-07

* Tentative approval of copackaged antiretroviral for PEPFAR availability, 2005-01-26

You can also use the Archive page to subscribe to the FDA's AIDS list serve, if you want to be notified by email of future announcements when they go out.

Uganda Study Found That Death Reduced HIV Prevalence; Did the Public Take Home the Wrong Message?

By John S. James

A major study reported at the Retroviruses conference (Boston, February 22-25, 2005) found that death of people with HIV accounted for most of the large decrease in the prevalence of HIV infection in the population, in a small area of Uganda that was intensively studied from 1994-2003 [1]. During that period, in the 50 villages studied in the Rakai district, the percentage of men with more than one sexual partner somewhat increased, condom use greatly increased but to well under 100%, and the incidence of new HIV infections remained relatively stable.

The researchers noted, "In summary, declines in Rakai HIV prevalence in the past decade are associated primarily with C and D" [1] -- meaning Condom use and Death, extending the "ABC" alphabet of Abstain, Be faithful, or use Condoms, the talking point that represents a much more comprehensive social and national mobilization to prevent HIV in Uganda.

The key point to keep in mind in understanding this study is that throughout the entire study period, the incidence of new HIV infections was relatively stable, mostly under 1.5% per

year. But before the study began, the incidence had been far higher, at least in some parts of Uganda (there are apparently no comparable data for the same villages). So the big reduction in new cases had already occurred before the Rakai study started.

This observation also explains the seemingly puzzling finding in the Rakai study that while HIV prevalence went down greatly in adults, it hardly changed in adolescents (it started low and remained low) [1]. Those who were adolescents during the study were not old enough to have been sexually active in the time of high transmission years before. So adolescents did not have the excess of deaths over new infections that led to the decline in prevalence overall.

Comment

The great decline in the percentage of people with HIV, reported by the Rakai study, happened because the number of deaths was far larger than the number of people newly infected. The many deaths in the study period were a dark shadow of an earlier time when the HIV incidence (new-infection rate) was much higher. The key question, then, is what brought the incidence down, before the study began?

It seems unlikely that it was condoms, since at the beginning of the Rakai study, fewer than 10% of the adults interviewed reported using them with their most recent non-marital partner (this percentage increased rapidly during the study). Unless condoms had been used previously and then abandoned, this low percentage could not have accounted for the big change in HIV prevalence.

Could the reduced rate of new infections be explained by the natural history of the epidemic? This seems unlikely because most other countries at a similar point in the epidemic had continuing increases in HIV incidence and prevalence, not the decline that Uganda had.

So behavior change in the period before

the study may be the most likely explanation for the reduction in the incidence of new infections then. During the study, the percentage of men age 15-49 reporting only one sexual partner in the last year remained greater than the percentage reporting two or more (this percentage increased somewhat during that time). Meanwhile, condom use greatly increased, giving men an additional opportunity to protect themselves and their partners -- but not enough to show statistically as a further overall reduction of HIV incidence, perhaps because the number of sexual partners also increased, and the median age of first sex declined in the study, especially among men.

What will likely be done now is to break down the data by villages, which probably differ in just when condoms were introduced, and just when the changes toward higher-risk behaviors occurred. Then a statistical analysis could better separate the effect of condom use, vs. number of sexual partners, vs. age of first sexual activity, on the incidence of new HIV infections in each village. Also, the database could be analyzed by each individual -- when did he or she report condom use, report multiple partners, or become HIV positive? This analysis was not presented at the meeting, probably because it had not been done by the time of this "late breaker" report of new information not available in time for the usual process of submission to the conference. This early report had overall rates for the entire study, not broken down by villages -- and the decrease in new infections due to condom use, and increase due to sexual risks, may have partly balanced each other. Once the Rakai study is fully analyzed, it may provide some of the best information available on what works and what does not.

Meanwhile, this study found some backsliding in the "B" part of "ABC" (reducing the number of sexual partner), in the Rakai district; clearly the uptake of condom use was more successful. But the results presented at the Retroviruses conference do *not* contradict the

possibility that an earlier large reduction in the number of sexual partners (in previous years, so it was not included in the data recently reported) was largely responsible for the decline in HIV prevalence that was seen during this study.

Incidentally, we see no blame; the researchers accurately reported their results, and the press correctly reported the researchers. But in the rush of late-breaker presentation and next-day reporting, no one made sure that the message received was accurate. It would be tragic if public misunderstanding led to less emphasis on any effective means of reducing the spread of HIV.

Note: This analysis is a work in progress. *AIDS Treatment News* is open to considering different views, making corrections if necessary, and perhaps publishing a followup article. Contact us at aidsnews@aidsnews.org.

References

1. MJ Wawer, R Gray, D Serwadda, and others. Declines in HIV prevalence in Uganda: Not as simple as ABC. 12th Conference on Retroviruses and Opportunistic Infections. Boston, February 22-25, 2005 [Abstract #27LB, available at <http://www.retroconference.org>].

Virginity Pledge Did Not Prevent Sexually Transmitted Infections

By John S. James

This study [1], published in April 2005, surveyed more than 11,000 U.S. adolescents when they were young adults (ages 18-24), and found that adolescent virginity pledges were not associated with lower rates of several sexually transmitted infection -- even though they were associated with several behavior changes that would have seemed to be protective. Although this survey did not ask about HIV, we thought it might interest our readers because it illustrates how an "abstinence only" intervention can fail to

reduce illness, and look like it is working when it is not.

In this large, long-term study, adolescents who consistently pledged virginity (about 7% of the 11,000, or 777 individuals) did have more behaviors that would be expected to be protective -- fewer partners, fewer risky partners, and delayed age of first sexual experience, with 25% of men and 21% of women being virgins at age 25 (compared to 7% and 6% for non-pledgers). The reason for the lack of health benefit, according to an editorial summary of the study [2], seems to be that pledgers were less likely to use condoms when they did become sexually active, were more likely to have anal or oral sex (almost always without a condom), and were less likely to seek and receive medical care if they did get a sexually transmitted infection. As one of the researchers told *The Washington Post* (2005-03-19), "The sad story is that kids who are trying to preserve their technical virginity are, in some cases, engaging in much riskier behavior."

The adolescents studied included only those who were in school, an acknowledged limitation of the study. The new report is from their third 5-year followup. About 80% of those studied never reported taking a virginity pledge, 13% said they had pledged but in a later 5-year followup said they had not (they were counted as inconsistent pledgers in the study), leaving only 7% of "consistent pledgers," who reported at least once that they had pledged and never said otherwise. [We suspect that the 13% were not lying or forgetful; rather the wording of the questionnaire did not allow them to report the real situation, that they had taken a pledge but abandoned it. Probably most of those in this position felt that the most truthful answer available to the question of whether they had ever taken a pledge was No, since otherwise they would be counted as abstinent when they were not -- suggesting that the real number of consistent pledgers may be less than 7%, since some who were no longer abstinent would have decided that the best of the

poor choice of answers was Yes.]

Most of those who pledged virginity did have sex before marriage (and before the date of the study interview). Sixty-one percent of consistent pledgers, 79% of inconsistent pledgers, and 90% of all non-pledgers said on the questionnaire that they did have sex before marriage.

Among consistent pledgers, 13% reported having only oral sex with one or more partners but no vaginal sex -- compared with only 2% of non-pledgers. This is the source of the news reports that pledgers were six times as likely to have oral sex. Condoms were very seldom used in these relationships.

The editorial [2] also notes that the debate over abstinence-only has not changed much since a century ago. "One camp advocates comprehensive education and skills. The other focuses only on eliminating adolescent sexual activity." The editorial also noted that abstinence is indeed 100% effective, as a personal choice -- but not as a public-health program used at a population level, which will always have a failure rate.

For us, the take-home message is that virginity pledges were not associated with reduction of sexually transmitted infections (again, HIV was not measured here) in this large and fairly representative U.S. study -- even though behavior changes that would seem to be protective were associated with the pledges. The reason for this paradox may have been that most of those who took the pledges did not stay with them, and then skipped precautions because they were reluctant to be seen as breaking their public pledge. This does not imply that other abstinence or behavior-change programs will also fail. The problem is not abstinence, but the ideological banning of all other prevention education when many, probably most, in the target audience are not going to stay abstinent.

References

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